REMARKS/ARGUMENTS

Claims 89 – 112 are pending.

No new matter is added by this amendment.

Double – Patenting Rejection

Claims 89-111 are rejected on the group of non-statutory obviousness-type double patenting over claims 1-22 of US Patent No. 7,544,370.

Claims 89-105 and 112 are rejected on the groups of non-statutory obviousness-type double patenting as being unpatentable over claims 1-21 of US Patent No. 7,550,153 and claims 1-7 of US Patent No. 7,553,498.

Applicants agree to file terminal disclaimers upon indication that the claims in the present application are otherwise in condition for allowance. Applicants reserve the right to present further arguments should the claims be amended in the future.

Claims 89-90 have been rejected under 35 USC 112, first paragraph, as failing to comply with written description. The examiner asserts that the claims raise a new matter rejection.

Applicants respectfully traverse this rejection.

It is noted that original claims 1 and 24 in this application recited "pantoprazole or an enantiomer thereof, or a salt or hydrate thereof". The specification also indicates that pantoprazole compounds include, "pantoprazole and enantiomers and salts and hydrates thereof." *See, e.g.,* on page 4, lines 10-20. This language encompasses pantoprazole sodium sesquihydrate, which is a specific hydrate of the sodium salt of pantoprazole illustrated in the examples. Thus, upon reading the specification, one would understand that the terms "salts" and "hydrates" can modify any of the preceding terms. The present claim does not add matter, but merely seeks

to make it clear to one of skill in the art that the pantoprazole compound in the recited claim is not in its free base form.

Reconsideration and withdrawal of this rejection is requested.

Claims 89-112 are rejected under 35 USC 103(a) as being unpatentable over US 5,753,265 in view of US Patent No. 5,997,903.

Applicants respectfully traverse this rejection.

The combined teachings of '265 and '903 fail to suggest a multiparticulate formulation which provides a pantoprazole formulation useful for patients who have difficulty swallowing the commercial tablet formulation. Nor do they suggest a multiparticulate formulation which is stable and bioequivalent to the commercial tablet, while providing a reduced lag time for onset of action and a longer interval for release compared with the tablet. Rather, it is only the present invention which provides the solution to stability problems in multiparticulates formulations (which are not compressed or tabletted).

Both the '265 patent and the '903 patent focus on tablet formulations. The '265 patent (it is noted that this corresponds to WO 96/01624) describes formulating an H+K+-ATPase inhibitor or one of its single enantiomers or an alkaline salt thereof, optionally mixed with alkaline compounds and further mixed with suitable constituents into a core material, which may be produced by extrusion/spheronization. However, the application focuses on a multiple unit tableted dosage form, and in each of its working examples describes layering or spraying the active component onto a seed. Further, the '265 patent teaches compression of its "pellets" into a tablet. This is not an element of the invention claimed in the present application. The '265 patent contains no suggestion of multiparticulates having an extruded spheroid core composed of a pantoprazole compound and surfactant in the ratio recited in the present claims.

US Patent No. 5,997,903 [issued in the name of Byk Gulden, now Altana] describes a compressed tablet which may contain the active compound pantoprazole in its core. There is no suggestion of any surfactant in the core.

It is also notable that the spheroid core of the present invention is prepared by mixing, followed by extrusion and spheronization. The core provided by the invention contains evenly dispersed active component and polysorbate 80 surfactant in the stated amounts with the other recited excipients as will be readily understood by one of skill in the art. The claimed core does not contain active layered over an inert material.

Thus, the combined teachings of the cited document fail to suggest the present invention.

Reconsideration and withdrawal of the invention is requested.

Claims 89-112 are rejected under 35 USC 103(a) as being unpatentable over US 6,159,499 and US 5,753,265 in view of US 5,997,903.

Applicants respectfully traverse this rejection.

No combination of the cited document suggests a multiparticulate containing this active compound in its core with the amount of polysorbate 80 surfactant, water, sodium bicarbonate and other the other components of the present multiparticulates. Nor does any of the prior art appear to even recognize the difficulties associated with achieving a stable pantoprazole multiparticulate, much less provide a solution to this problem.

The teachings of the combination of cited documents provide motivation NOT to combine their teachings. The '499 patent specifically discusses the '265 patent in its background section, and distinguishes itself over this document. The '499 patent specifically teaches the exclusion of alkaline-reacting compounds and mannitol from the core material, both of which are permitted in the '265 patent. Thus, the '499 patent would motivate one of skill in the art to avoid combining the teachings of the

'499 and '265 patents to produce the formulation used in the invention, as these two documents are mutually incompatible.

Further, even if these two documents could be combined, the combination of these documents with US Patent No. 5,997,903 [issued in the name of Byk Gulden, now Altana] fails to suggest the present invention. The '903 patent describes a compressed tablet which may contain the active compound pantoprazole in its core. There is no suggestion of polysorbate 80 surfactant in the core in combination with the other elements of the multiparticulates of the present invention.

The '499 patent expressly excludes the active principal from being in the form of an alkaline salt, and teaches that the core be composed of a plurality of "nuclei". The active principal and nuclei are mixed and then compressed together. Thus, the '499 patent teaches away from the use of multiparticulate extruded/spheronized core containing a pantoprazole and the excipients recited in the present claims, coated with an inner coat, and further coated with an enteric coat, in which each *multiparticulate* has the average size recited in the present claims. However, even if the teachings of '265 and '499 are combined, the present invention is not rendered obvious. The cited documents does not suggest the average size of the finished multiparticulates recited in the claimed invention. Nor do these documents suggest the amount of polysorbate 80, the amount of sodium carbonate, the amount of water, or the other components provided in the core of the present invention, much less the other elements of the multiparticulates, as provided by the claims. Further, the present invention does not provide for tabletting or compression of the multiparticulates, but intends for them to be delivered in particulate form to permit delivery to individuals having difficulties swallowing.

For these reasons, applicants request reconsideration and withdrawal of this rejection.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper, or credit any overpayment in any fees, to our Deposit Account, Number 08-3040.

Respectfully submitted
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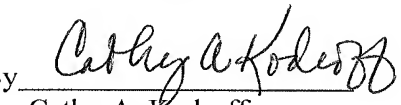
By 

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